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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,290	04/12/2000	Tatsuya Sasakawa	0018-1098-0	6669

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/11/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/548,290	Sasakawa
Examiner	**Art Unit**
Anne Marie Wehbé	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 9, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *29-37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *29-37* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/9/02 has been entered.

Applicant's amendment received on 10/9/02 has also been entered. The applicant is reminded that the after-final amendment received on 8/7/02 was not entered, see the advisory action mailed on 9/18/02, paper no. 11. Claims 21-28 have been canceled. New claims 29-37 have been added. Claims 29-37 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Claim Rejections - 35 USC § 112

The rejection of claims 21-28 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's cancellation of the claims.

Claim Rejections - 35 USC § 103

The rejection of canceled claims 21-26 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. in view of Yasue et al. is maintained over new claims 29-36. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that Morita et al. does not teach the specific pathogen free (SPF) condition recited in the claims because Morita administered live mites to the model mice. Morita et al., however, not only teaches the use of NC mice, an inbred strain of fancy mice established in 1955, which have been bred under specific pathogen free conditions and renamed NC/kuj, but further specifically teaches that the mice exposed to live mites were kept in clean rooms with air filtration (Morita et al., see in particular page 41, column 2, paragraph 2). The fact that these mice, bred under SPF conditions, are then administered a live mite does not detract from the teachings of breeding and maintaining these NC/kuj mice under sterile conditions. It was well know at the time of filing that maintenance of this NC mouse strain in non-sterile (conventional) conditions results in the spontaneous development of atopic dermatitis-like skin lesions (Morita et al., abstract). In order to prevent other environmental antigens from affecting the mite treated mice, Morita et al. maintained the treated mice in sterile conditions. In fact, Morita et al. specifically states that the, "effect of other environmental allergens were neglected in our study

because these mice were kept in clean rooms with air filtration" (Morita et al., page 41). Thus, Morita et al., while using live mite instead of mite antigen, Morita et al. does not teach away from the concept of keeping both the untreated and treated NC mice in sterile conditions. In addition, in regards to the alleged advantages of the claimed mouse over the Morita et al., the rejection of record is not based solely on the teachings of Morita et al., but on the combination of Morita et al. and Yasue et al.

In regards to the teachings of Yasue et al., the applicant argues that Yasue does not teach that mite extract can cause atopic dermatitis like symptoms in NC/Nga mice. Yasue et al. has been cited for the demonstration that a mite extract can cause substantial allergic reactivity in mice. Mite extract is a crude preparation that contains all of the major antigenic proteins expressed by the live mite. Based on the demonstration by Morita that antigens from live mites can cause atopic dermatitis like symptoms, the skilled artisan would have had a reasonable expectation that a crude mite extract which contains all the same antigens would also be capable of generating the same symptoms in view of the potency of the mite extract in inducing allergic responses in mite sensitive mice. Note that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. 103, all that is required is a reasonable expectation of success. See *In re O"Farrell*, 7 USPQ2d 1673 (CAFC 1988).

The applicant further argues that neither Morita or Yasue provide motivation for combining the teachings of the two references to suggest the instant invention. The applicant states that the office has not provided any evidence of motivation for combining the

administration of mite extract with the method of making a mouse model for atopic dermatitis taught by Morita et al. which uses live mites. The rejection of record, however, clearly states that the skilled artisan would be motivated to use a mite extract over live mites in order to standardize the amount of antigen to which each mouse is exposed, thereby ensuring a homogenous population of exposed mice. Thus, in order to produce a more homogeneous population of mite sensitized mice for use as an animal model of human allergic disease, it would have been *prima facie* obvious to the skilled artisan to substitute mite extract injection as taught by Yasue et al. for the live mite exposure taught by Morita et al. in the method of producing a murine model of atopic dermatitis taught by Morita et al. Further, based on the successful use of mite extracts to generate allergic responses in mice as taught by Yasue et al., the skilled artisan would have had a reasonable expectation of success in generating a mouse model of atopic dermatitis by exposing specific pathogen free NC mice to a mite extract under sterile conditions. Regarding "evidence" of motivation, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Furthermore, it is noted, that the test for combining references is not what the individual references themselves suggest, but rather what the combination of disclosures taken as a whole would have suggested to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392, 170

USPQ 209 (CCPA 1971). For the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references. *In re Nilssen*, 7 USPQ2d 1500 (Fed. Cir. 1988). Also, "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin*, 443 F2d. 1392, 170 USPQ 209, 212 (CCPA 1971).

The rejection of canceled claims 27-28 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. in view of Yasue et al. and Hiroi et al. is maintained over new claim 37. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that Hiroi et al. does not describe producing mice suitable for an animal model for atopic dermatitis. The applicant is reminded that the rejection of record is not based solely on the teachings of Hiroi et al., but on the combined teachings of Morita et al., Yasue et al., and Hiroi et al.. Morita et al. teaches that the administration of ivermectin to the mice reduces anti-mite IgE levels and skin lesions (Morita et al., pages 41-42). This demonstrates that the mice are suitable for testing potential therapeutic agents. Hiroi et al. further supplements Morita et al. by providing motivation for testing potential therapeutic agents in mouse models of atopic dermatitis. Hiroi teaches that the standard model for spontaneous atopic dermatitis, NC

mice raised under conventional and not specific pathogen free conditions, can be used to screen for therapeutic agents. Specifically, Hiroi teaches that FK506 ointment, not betamethasone valerate ointment, was determined to be effective in suppressing and inhibiting symptoms of atopic dermatitis when applied to NC mice both before and after the development of dermatological symptoms (Hiroi et al., page 176 and Figure 1, 2, and 3). Thus, in view of the motivation provided by Hiroi et al. for using murine models of atopic dermatitis to determine the effectiveness of agents in preventing or inhibiting atopic dermatitis, it would have been *prima facie* obvious to screen agents for effectiveness against atopic dermatitis using the mouse model taught by Morita et al. in view of Yasue et al. Further, based on the demonstration by Morita et al. that ivermectin is useful for treating atopic dermatitis like symptoms in the mouse model of atopic dermatitis developed by Morita et al., the skilled artisan would have had a reasonable expectation of success in testing agents for effectiveness against atopic dermatitis using the mouse model taught by Morita et al. in view of Yasue et al.

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action

after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbe, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbe

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER